

Remarks/Arguments:

Reconsideration of the application is requested.

Claims 1 to 33 are now in the application. Claims 1 to 12 and 26 to 33 are subject to examination and claims 13 to 25 have been withdrawn from examination. Claim 27 has been amended. Claims 31 to 33 have been added.

In items 3 to 7 on pages 2 to 4 of the above-identified Office action, claims 1, 2, 5, 6, 9 to 11, 27, 29, and 30 have been rejected as being fully anticipated by U.S. Patent No. 5,037,021 to Mills et al (hereinafter "Mills") under 35 U.S.C. § 102.

As will be explained below, it is believed that claims 1 and 29 were patentable over Mills in their original form and, therefore, these claims have not been amended to overcome Mills.

Before discussing the prior art in detail, it is believed that a brief review of the invention as claimed, would be helpful. Claim 1 calls for, *inter alia*, a medical method, including:

advancing a clip over body tissue, the clip having two arms each having a respective piercing portion and a

bridge coupling the two arms, such that the body tissue is located between the two arms and such that the clip applies force to the body tissue; and

subsequently bending the piercing portion of at least one of the two arms through more than one half a thickness of the body tissue.

Claim 29 calls for, *inter alia*, a medical method, including the steps of:

providing a clip having two arms each having a respective piercing portion and a bridge coupling the two arms;

advancing a clip over body tissue folded on itself to form a first portion of a fold and a second portion of the fold such that the first and second portions are located between the two arms and such that the clip applies force to the body tissue; and

subsequently bending the piercing portion of at least one of the two arms through the first portion of the fold and at least partially through the second portion of the fold.

It is noted that the Examiner's comments directed to claim 1 and 29 rejection by Mills are found on pages 2 and 3, 4, and 7 of the final Office action.

As set forth above, each of the two arms of the clip has a respective piercing portion. Thus, claims 1 and 29 provide for a clip with two piercing portions. Nowhere does Mills disclose or suggest a clip with two piercing portions and the Examiner's comments are silent with respect to this claimed feature and, in fact, clearly provides that only "one of them is bent through the whole thickness of the *both portions of tissue* [see progression from Figure 5a to 5c]." Because Mills does not disclose a clip with two piercing portions, Mills cannot anticipate claims 1 or 29.

The Examiner has further commented that a description of the "piercing portion" is not clear. Applicants respectfully disagree. Many instances of the specification provide that the "piercing portion" is that portion of the clip that pierces the tissue. See, for example, page 8, lines 6 to 7, page 24, lines 16 to 18 (see retainer 222), page 25, lines 15 to 25 (see retainer 320, 322), page 26, lines 10 to 19 (see retainer 420, 422), and FIGS. 17 to 25. Mills does not have a clip with two piercing portions, each of which able to pierce the skin.

As for claim 27, the rejection has been noted and this claim has been amended in an effort to even more clearly define the invention of the instant application. Support for the changes is found, for example, in FIGS. 18, 20, 22 to 25 of the instant application.

Claim 27 calls for, *inter alia*, a medical method, including the steps of:

providing a clip having:

two arms each having a piercing portion; and

a bridge coupling the two arms;

folding body tissue to form a folded portion extending along a longitudinal direction;

advancing the clip over the folded portion of body tissue in the longitudinal direction to place the folded portion between the two arms and to apply force to the folded portion with the clip; and

bending the piercing portion of at least one of the arms through more than one half a thickness of the folded portion at an angle to the longitudinal direction.

For the reasons set forth above, Mills does not anticipate claim 27, as amended. Dependent claims 2 to 12, 26, 28, and 29 are believed to be patentable as well because they all are ultimately dependent on claims 1, 27, or 29.

As is known, conventional staples (whether medical or clerical) pierce sheets of a material orthogonal to the plane of the sheets and bend the prongs that pierce through and already extend beyond the sheets in a direction along the sheets to hold the sheets together and to, thereby, provide a compressing/holding force in the piercing direction, specifically, between the head of the staple and the bent-over tips.

FIGS. 5a to 5c of Mills clearly show that the Mills staple 209 is very similar to a staple from, for example, a SWINGLINE® desk stapler. In particular, the single portion of the Mills staple that is to pierce the tissue enters the tissue perpendicular to the tissue fold while an anvil is placed on the opposite side of the tissue. Then, after completely piercing the tissue 216, the piercing portion is bent

subsequently by the anvil 260 disposed on the other side of the piston 205. Simply put, the Mills stapler pierces straight portions orthogonally through the tissue and subsequently bends the straight portions with an external device (anvil 260) positioned on the opposite side of the tissue to cause the clenching force.

The piercing portion of the invention of claims 1, 27, and 29, however, do not perform in this way. The clip of these claims is advanced over the body tissue in a longitudinal direction of the body tissue to be clipped. After advancing thereover, the piercing portion is caused to bend and, because of such bending, the tissue is pierced. Because Mills does not disclose the features of claims 1, 27, or 29, it cannot be said to anticipate these claims.

In items 8 and 9 on pages 4 to 5 of the above-identified Office action, claims 1, 3, 4, 12, and 26 have been rejected as being fully anticipated by U.S. Patent No. 5,582,611 to Tsuruta et al. (hereinafter "Tsuruta") under 35 U.S.C. § 102.

Claim 1 calls for, *inter alia*, a medical method, including:

advancing a clip over body tissue, the clip having two arms each having a respective piercing portion such that the body tissue is located between the two arms; and

subsequently bending the piercing portion of at least one of the two arms through more than one half a thickness of the body tissue.

Simply put, the body tissue mentioned in claim 1 refers to the tissue between the two arms. In each claim, the piercing portion of the clip pierces entirely through a first half of the folded tissue therebetween and, then, into the second half.

As shown clearly in Tsuruta, especially in FIGS. 39C, 42C, 43C, 49C, 53D, 55D, 59A, and 59B, each side of the staple 22a, 22b only pierces to a point where one side 22a of the staple 22 touches the other side 22b. Therefore, each piercing side only pierces *up to the half-way point* of the tissue therebetween. This extent is a required limitation of Tsuruta and nowhere does Tsuruta disclose or suggest having either side (22a, 22b) of the staple 22 pierce more than half of the way through the tissue between the two sides 22a, 22b. In fact, the Examiner admits on page 5 of the Office action that *"the tips of the two arms contact each other."* (Emphasis

original.) It is noted that FIGS. 57C, 60B, 60C, 62B, and 62C show embodiments where the tips of the staple are not even touching -- so that they do not entirely pierce through a tissue portion.

Applicants have added new claim 33, which is identical to claim 1 in all but two respects. First, the clip is advanced over "two thicknesses of body tissue." Subsequently the piercing portion of at least one of the two arms is bent through "more than one of said thicknesses of said body tissue." Tsuruta does not disclose or suggest piercing more than a thickness of a body tissue as shown in FIGS. 39C, 42C, 43C, 49C, 53D, 55D, 59A, 59B, 57C, 60B, 60C, 62B, and 62C.

The Examiner contends that Tsuruta discloses, in FIGS. 42 and 43, that the Tsuruta "clip (22) has two arms and bridge coupling the arms, as shown in Figure 61." Further, the Examiner contends that "the clip applies force to the body tissue" and that "*[e]ach arm is bent through the entire thickness of the body tissue such that the tips of the two arms contact each other.*" (Emphasis original.)

The final rejection is entirely silent on the Tsuruta clip 22 "advancing over" any body tissue. This is because the Tsuruta clip does not disclose or suggest *advancing* the clip 22 over

body tissue. Tsuruta does not "advance over" the tissue because, as shown clearly in FIGS. 39A to 39C, 42A to 42C, 43A to 43C, 49A to 49C, 53A to 53D, 55A to 55D, 59A to 59B, 60A to 60C, and 62A to 62C, the Tsuruta clip 22 only *pierces into* the tissue. In contrast, claim 1 clearly provides that a clip is *advanced over* the body tissue. Because Tsuruta does not disclose or suggest such a feature, it cannot be said to anticipate claim 1.

In items 10 and 11 on pages 5 to 6 of the above-identified Office action, claims 7 and 8 have been rejected as being obvious over mills in view to Bolanos et al (U.S. 5,571,116; hereinafter "Bolanos") under 35 U.S.C. § 103.

Insofar as claim 1 is believed to be allowable, and due to the fact that claims 7 and 8 ultimately depend upon claim 1, the rejections of these claims is now believed to be moot.

Just like Mills, Bolanos' staple 30 is similar to a conventional desktop stapler. Specifically, the portion of the staple 30 that is to pierce the tissue enters the tissue perpendicular to the tissue fold while an anvil 26 is placed on the opposite side of the tissue (see anvil recesses 33 in FIG. 6A, 6B, and 8). Then, after completely piercing the tissue, the pierced and orthogonally extending portion is bent

by the anvil 26 disposed on the other side of the staple ejector 28. See Bolanos at FIGS. 6B and 8. Nowhere does Bolanos disclose or suggest "advancing a clip over body tissue" as set forth in claim 1. Thus, Bolanos cannot suggest claim 1 of the instant application.

Applicants have added new claims 31 to 33. Support for these claims may be found at least from the original claims. It is respectfully believed that these claims are not shown or suggested by the cited prior art references for all of the reasons set forth above.

It is accordingly believed to be clear that none of the references, whether taken alone or in any combination, either show or suggest the features of claims 1, 27, 29, 31, 32, or 33. Claims 1, 27, 29, 31, 32, and 33 are, therefore, believed to be patentable over the art. The dependent claims are believed to be patentable as well because they all are ultimately dependent on claims 1, 27, or 29.

ALLOWANCE OF WITHDRAWN CLAIMS:

In the election of species requirement, the Examiner stated that upon allowance of a generic claim, applicants would be entitled to consideration of the claims of Species 2. It is noted that the Species 2 feature of the method of applying a

clip with unconnected arms can be read on claim 1 because claim 1 is broad enough to encompass both connected and unconnected clip arms. See new claim 28. Therefore, claim 1 is generic to Species 2 and claims 13 to 18 should be allowed as well.

In view of the foregoing, reconsideration and allowance of claims 1 to 18 and 26 to 32 are solicited.

In the event the Examiner should still find any of the claims to be unpatentable, counsel would appreciate receiving a telephone call so that, if possible, patentable language can be worked out. In the alternative, the entry of the amendment is requested, as it is believed to place the application in better condition for appeal, without requiring extension of the field of search.


If an extension of time for this paper is required, petition for extension is herewith made.

The extension fee for response within a period of one (1) month pursuant to Section 1.136(a) in the amount of \$110.00 in accordance with Section 1.17 is enclosed herewith.

Applic. No. 10/010,244
Amdt. Dated August 16, 2004
Response to Office Action of August 13, 2003

Please charge any other fees that might be due with respect to
Sections 1.16 and 1.17 to the Deposit Account of Lerner and
Greenberg, P.A., No. 12-1099.

Respectfully submitted,



For Applicants

GLM:cgm

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August 16, 2004

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